

REMARKS

The Office action dated June 8, 2011 is acknowledged. According to the Office action, claims 1-20 are pending in the application, claims 5-8, 11 and 15 have been withdrawn and claims 1-4, 9, 10, 12-14 and 16-20 have been rejected. By the present response, claim 1 has been amended for purposes of clarification, support for which may be found throughout the specification such as at paragraphs [000021] – [000024]. Claim 21 has been added, which is based on amended claim 1 and dependent claims 3 and 4, support for which may also be found throughout the specification such as at paragraphs [000021] – [000024]. Paragraph [000023] of the specification is also amended for purposes of clarification. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Rejection of claims 1-4, 9, 10, 12-14 and 16-20 under 35 U.S.C. 103(a)

Claims 1-4, 9, 10, 12-14 and 16-20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over DE 10053375 (Degen, et al.), as optionally evident by the provided articles “4-aminobenzoic acid,” encyclopedia, “CINNAMIC ACID” product identification, “Benzophenone,” Ingredients Feedback Science and “Lacquer definition,” Your Dictionary, and in view of U.S. Patent No. 5,372,819 (Godbey, et al.). The Examiner states in the Office action that Degen, et al. disclose a transparent transdermal therapeutic system (TTS) that contains photosensitive active ingredient and that the TTS comprises colorless active ingredients contained in the polymer matrix and has a backing layer. The Examiner also states that the matrix and the backing comprise UV absorbent

that does not have pharmacological or therapeutic effect and that UV absorbent are homogenously distributed as dissolved or dispersed form in the matrix and in the backing layer.

As further explained at pages 4-5 of the Office action, the Degen, et al. reference teaches the limitations of the presently claimed invention according to the Examiner. However, the Examiner acknowledges that although Degen, et al. teach UV absorbent in the backing layer to protect the photosensitive drug and UV absorbent having color, the reference does not explicitly teach pigment or dye in the backing layer. The Examiner refers to Godbey for teaching a transdermal patch comprising a backing layer that may be transparent and preferably contains pigments. The Examiner thus concludes that it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal patch having a backing containing UV absorbent as taught by Degen, et al. and to replace the UV absorber by pigment or to further add pigment to the backing as taught by Godbey. The Examiner also states that one would have been motivated to do so because Degen, et al. desired to protect the transdermal patch from light by adding UV absorber and because Degen, et al. preferred to add pigment to the backing for the same purpose. According to the Examiner, one would reasonably expect formulating transdermal patch having backing comprising pigment that successfully protect photosensitive active agent in the patch.

Regarding the claimed lightness color value of present claim 1 and numeric values of present claim 17, the Examiner states that such properties are intrinsic properties of the patch taught by Degen, et al. combined with Godbey because the combination of the

references teaches a patch that has the same structure and made from the same materials used by the Applicant. The Examiner also states that regarding testing of the patch to determine the lightness color value and the method of testing of present claim 16, these are not part of the claimed transdermal patch but rather is only an *in-vitro* diagnostic test that is expected to provide the same results obtained from two similar transdermal delivery devices built from the same materials and tested under the same circumstances. In this regard, the Examiner states that the burden is on the Applicant to show that the claimed testing process resulted in novel and unobvious difference between the claimed product and prior art product since the Patent Office does not have the facilities for preparing the claimed materials and comparing them with the prior art inventions.

Regarding coating of the dye or pigment on the backing layer of claim 4 using lacquer of claim 13, the Examiner states that Degen, et al. teach homogenous distribution or solvating the UV absorber in the backing material and homogenous distribution will provide UV absorber on the surface of the backing forming coating. The Examiner further states that the lacquer is nothing but solvent (per the definition provided by “Your Dictionary”), and solvating the UV absorber in a solvent before application to the backing reads on lacquer claimed by present claim 13.

Thus, the Examiner concludes that absent any evidence to the contrary and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the presently claimed invention and thus the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

It is respectfully submitted that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine or modify the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider the teachings of the cited prior art alone or in combination, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered.

The Applicants respectfully disagree with the Examiner's conclusion that the presently claimed invention is unpatentable over Degen, et al., as optionally evident by the provided articles "4-aminobenzoic acid," encyclopedia, "CINNAMIC ACID" product identification, "Benzophenone," Ingredients Feedback Science and "Lacquer definition," Your Dictionary, and in view of Godbey, et al. In particular, the combination of teachings of these references fails to teach each and every limitation of the presently claimed invention.

As indicated by the Examiner in the Office action, the Degen, et al. reference fails to explicitly teach pigment or dye in the backing layer and reference is made by the Examiner to the Godbey, et al. patent for teaching transdermal patch comprising a backing layer that may be transparent and preferably contains pigments.

As amended herewith, the presently claimed invention has been clarified to recite that the present invention is a medical active substance patch comprising a matrix of monolayer or multilayer configuration and a backing layer that is connected with the matrix. The backing layer has one side averted from the skin, and at least one layer of the matrix contains a pharmaceutically active substance, and an ingredient selected from the group consisting of at least one coloured ingredient, and at least one colourless ingredient being colourless in an initial state and tending to discolour or to discolour(s) during storage or to discolour during the application period. The at least one coloured ingredient and the at least one colourless ingredient are selected from the group consisting of a pharmaceutically active substance and an auxiliary agent. The active substance patch of the present invention also comprises at least one substance selected from the group consisting of dyes and pigments, as noted by the Examiner.

However, the Examiner indicates in the Office action that the presently claimed invention comprises the dye or pigment in the backing layer. As amended, the claims recite that the dye or pigment is contained in at least one layer of the matrix and or is associated with the backing layer. In other words, the present claims recite that the dyes or pigments may be contained in at least one matrix layer and/or contained in a coating (i.e., not directly in the backing layer) that is coated onto the side of the backing layer that is averted from the skin. The prior art clearly fails to teach or disclose a medical active substance patch which contains at least one of a dye or pigment contained in the at least one matrix layer and/or contained in a coating on the backing layer, as presently claimed.

In this regard, the Examiner also argues that Degen, et al. teach a homogenous

distribution or solvating the UV absorber in the backing material, and that a homogenous distribution will provide UV absorber on the surface of the backing forming a coating. The Applicant respectfully disagrees with this conclusion. A homogenous distribution according to Degen, et al. implies a uniform distribution in the backing material. A homogenous distribution in the backing material of Degen, et al. would not necessarily mean there would be a distribution on the surface of the backing material, let alone in a separate coating on the surface of the backing material. A homogenous distribution in the backing material of Degen, et al. fails to teach a coating covering the backing layer on the side averted from the skin, and where the coating contains at least one substance selected from the group consisting of at least one dye and at least one pigment.

Still further, Degen, et al., as indicated by the Examiner, teach homogenous distribution in the backing material. A homogenous distribution in the backing material would clearly teach away from the presently claimed invention, which recites the pigment or dye contained in a coating covering the backing layer on the side averted from the skin and not in the backing layer. The pigments or dyes of the presently claimed invention would not be contained in the backing layer, as suggested by the Degen, et al. reference.

The same holds true for Godbey, et al., which, according to the Examiner, teach transdermal patch comprising backing layer that may be transparent and preferably contains pigments. The pigments or dyes of the presently claimed invention would not be contained in the backing layer, as taught by the Godbey, et al. reference and as indicated by the Examiner. As such, Godbey, et al. would also teach away from the presently claimed invention where the pigments or dyes are not contained in the backing layer but

rather are contained in a coating covering the backing layer on the side averted from the skin. In turn, the Godbey, et al. reference clearly fails to make up for the deficiencies of Degen, et al. and teaches away from the presently claimed invention.

It is therefore respectfully submitted that the present invention defined in the present claims is patentably distinguishable over the combination of prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the presently claimed invention are not set forth in the cited prior art references, alone or in combination with any of the cited secondary references. Moreover, one skilled in the art would not be motivated to combine said references or to modify the prior art references to arrive at the presently claimed invention. Therefore, the Applicants strongly request that this rejection be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the anticipation and obviousness-type rejections be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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